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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,592	07/08/2003	Louis Johan Wagenaar	BAY-001.01 (24877-001.01)	8286
25181	7590	10/05/2004	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			AZPURU, CARLOS A	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/615,592

**Applicant(s)**

WAGENAAR, LOUIS JOHAN

**Examiner**

Carlos A. Azpuru

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,9-12,17-19,24-26 and 29 is/are rejected.
- 7) ☒ Claim(s) 3,4,6-8,13-16,20-23,27 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5, 12, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the use of certain language used in the Markush Group. Phrases that introduce open ended language to the Markush Group render the metes and bounds of the Markush Group indefinite. Applicant refers to "other antioxidants", "other enzymes", "other bee products", and "other minerals" in the claim. These terms are not acceptable to proper Markush language.

Regarding claims 2, 5, 12 and 19, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Also, the term "peptides" is indefinite since this would not particularly point out which peptides are beneficial to the claimed invention. The term can now include toxins or enzymes which may cause damage to the eye. Further, other

members of the Markush group such as EGF, PDGF, FGF are also peptides.

Clarification is requested.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 9 -12, 17-19, 24, and 25 are rejected under 35

U.S.C. 102(b) as being clearly anticipated by Park et al.

Park et al disclose contact lenses impregnated with solutions of Vitamin A, Vitamin E, ascorbic acid, and other antioxidants such as glutathione (see Abstract; col. 4, lines 7-42). The compounds are used to prevent proteinaceous deposits. Kits only contain the lenses and impregnating solution. As such, they are clearly disclosed by Park et al since applicant's kit is based solely on the contact lens composition, not on any novel packaging or kit formulation. The instant claims are clearly anticipated by Park et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 25 and 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of EP 0 473 159 (EP'159).

Park et al disclose contact lenses impregnated with solutions of Vitamin A, Vitamin E, ascorbic acid, and other antioxidants such as glutathione (see Abstract; col. 4, lines 7-42). The compounds are used to prevent proteinaceous deposits. Kits merely contain the contact lens and impregnating material. Park et al however do not disclose the use of Vitamin A as a treatment for dry eye.

EP'159 clearly teach that Vitamin A solutions can be used to treat dry eye (See Abstract). It would have been well within the skill of the ordinary practitioner to use a vitamin A solution in a contact lens as taught by Park et al, and further, to use that impregnates contact lens as a treatment of dry eye as taught by EP'159. Those of ordinary skill would have expected similar therapeutic results in the treatment of dry eye given the teachings of Park et al which discloses a contact lens that may have a Vitamin A solution within it, and further in view of EP'159 which specifically teach that Vitamin A solutions may be used to treat dry eye. Therefore, the use of the instantly claimed lens as a treatment of dry eye would have been obvious given the teachings of Park et al, in view of EP'159.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tuse et al.

Tuse et al disclose an antimicrobial peptide for use in disinfecting of contact lenses (see Abstract). Those of ordinary skill would therefore find it well within their skill to claim the instant peptide solution with a reasonable expectation of disinfecting properties given the disclosure of Tuse et al. It would have been obvious to claim the instant composition in view of the teachings of Tuse et al.

Claims 3,4,6-8, 13-16, 20-23, 27-28 are objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

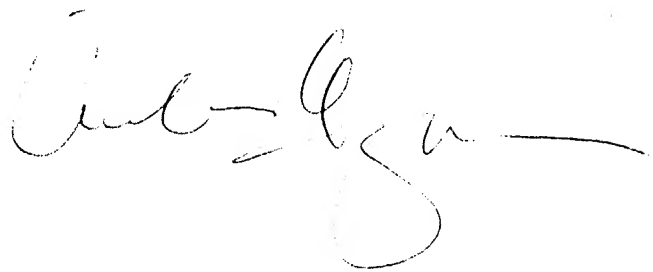
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602.

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The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ca

A handwritten signature in black ink, appearing to read 'Carlos A. Azpuru', with a long horizontal line extending to the right.

CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500